

regarding the technical and scientific merits of the study: "A Cohort Mortality Study with a Nested Case-control Study of Lung Cancer and Diesel Exhaust Among Non-metal Miners," being conducted jointly by NIOSH and NCI.

Matters to be Discussed: Agenda items include short presentations concerning the study protocol by the study investigators, comments from the Review Panel members, responses and discussion of comments submitted by others who have reviewed the protocol, and discussion open to all meeting attendees. Viewpoints and suggestions from industry, labor, academia, other government agencies, and the public are invited. Written comments will be part of the review, and should be received by the contact person listed below no later than November 1, 1996. Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Michael Attfield, Ph.D., NIOSH Project Director, Division of Respiratory Disease Studies, M/S 234, 1095 Willowdale Road, Morgantown, West Virginia 26505-2888, telephone 304/285-5751, fax 304/285-5861.

Dated: October 8, 1996.

Nancy C. Hirsch,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96-26300 Filed 10-11-96; 8:45 am]

BILLING CODE 4160-19-M

Food and Drug Administration

[Docket No. 96F-0370]

Dover Chemical Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Dover Chemical Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of 3,9-bis[2,4-bis(1-methyl-1-phenylethyl) phenoxy]-2,4,8,10-tetraoxa-3,9-diphosphaspiro[5.5]undecane as an antioxidant and/or stabilizer for olefin polymers intended for use in contact with food.

DATES: Written comments on the petitioner's environmental assessment by November 14, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug

Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3081.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 6B4521) has been filed by Dover Chemical Corp., 3676 Davis Rd. NW., Dover, OH 44622. The petition proposes to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the safe use of 3,9-bis[2,4-bis(1-methyl-1-phenylethyl) phenoxy]-2,4,8,10-tetraoxa-3,9-diphosphaspiro[5.5]undecane as an antioxidant and/or stabilizer for olefin polymers intended for use in contact with food.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before November 14, 1996 submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the Federal Register. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Dated: October 2, 1996.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 96-26372 Filed 10-11-96; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 94E-0099]

Determination of Regulatory Review Period for Purposes of Patent Extension; Neutrexin™; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting the notice that appeared in the Federal Register of August 30, 1994 (59 FR 44737). The document announced FDA's determination of the regulatory review period for purposes of patent extension for Neutrexin™ (trimetrexate glucuronate). The document was published with an error in one of the dates stated as part of the regulatory review period and requires additional clarification between the patent extension applicant's records and FDA's records.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

In FR Doc. 94-21280, appearing on page 44737 in the Federal Register of Tuesday, August 30, 1994, the following corrections are made:

On page 44737, in the second column, in the second complete paragraph, in the fourth line, "1,934" is corrected to read "1,931"; and in the sixth line, "317" is corrected to read "320"; in the same column, in the third complete paragraph, in the eighth line, "However," is removed; in the eleventh line, "March 10, 1987. FDA" is corrected to read "March 10, 1987. The applicant has documentation to suggest that an FDA official orally removed IND 29,796 from clinical hold on September 2, 1987. However, FDA"; in the fourteenth line, "clinical hold" is corrected to read "clinical hold via letter"; and in the same column, in the last paragraph, beginning in the fifth line, "February 4, 1993" is corrected to read: "February 1, 1993"; and the last two sentences are corrected to read: "FDA has verified the applicant's claim that the new drug application (NDA) for Neutrexin™ (NDA 20-326) was initially submitted on February 1, 1993."

Dated: October 8, 1996.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 96-26301 Filed 10-11-96; 8:45 am]

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